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IN THE

Supreme Court of the United States

OCTOBER TERM, 2001

FESTO CORPORATION,

Petitioner,

v.

SHOKETSU KINZOKU KOGYO KABUSHIKI CO., LTD.,

Respondents.

On Writ Of Certiorari To
The United States Court Of Appeals
For The Federal Circuit

BRIEF OF AMICUS CURIAE IN SUPPORT OF REVERSAL OF THE JUDGMENT BELOW

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BRIEF OF AMICUS CURIAE IN SUPPORT OF REVERSAL OF THE JUDGMENT BELOW

WISCONSIN ALUMNI RESEARCH FOUNDATION; THE REGENTS OF THE UNIVERSITY OF CALIFORNIA; MASSACHUSETTS INSTITUTE OF TECHNOLOGY; WASHINGTON RESEARCH FOUNDATION; UNIVERSITY OF PENNSYLVANIA; UNIVERSITY OF MINNESOTA; THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY; SUNY RESEARCH FOUNDATION; CORNELL RESEARCH FOUNDATION, INC.; UNIVERSITY OF FLORIDA; UNIVERSITY OF UTAH; OREGON HEALTH & SCIENCE UNIVERSITY; UNIVERSITY OF TEXAS-MEDICAL BRANCH; UNIVERSITY OF VERMONT; M.D. ANDERSON CANCER CENTER-HOUSTON; COLD SPRING HARBOR (WOODS HOLE OCEANOGRAPHIC CENTER); THE AMERICAN COUNCIL ON EDUCATION; THE ASSOCIATION OF AMERICAN UNIVERSITIES; THE NATIONAL ASSOCIATION OF STATE UNIVERSITIES AND LAND-GRANT COLLEGES; COUNCIL ON GOVERNMENTAL RELATIONS; AND RESEARCH CORPORATION TECHNOLOGIES.

INTEREST OF AMICUS CURIAE

Amicus curiae include leading research universities and related non-profit institutions in the United States that conduct and support research and development activities in connection with their primary educational mission. App. at 1a.[1] Following the enactment of the Patent and Trademark Law Amendments Act of 1980, P.L. 96-517, as amended in P.L. 98-620, Pub. L. 99-502, and Pub. L. 106-404, commonly known as the Bayh-Dole University and Small Business Procedures Act (current version at 35 U.S.C. §§ 200-212 (2001) (hereinafter the Bayh-Dole Act)), these institutions embarked on a historic enterprise by transferring their patented technology into the private sector to promote innovation and economic development.

The ability of *amicus curiae* to continue this activity is dependent on whether they may rely on the federal courts to protect their patents under the doctrine of equivalents, as unanimously affirmed by this Court in *Warner-Jenkinson Co.* v. *Hilton Davis Chemical Co.*, 520 U.S. 17 (1997) ("*Warner-Jenkinson*"). The majority decision in *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 234 F.3d 558 (Fed. Cir. 2000) (en banc) ("*Festo*"), however, recently held that federal courts may no longer apply this doctrine to determine whether non-literal infringement has occurred if a claim is amended during the prosecution process for any reason that "relates to" the statutory requirement for a patent. *Id.* at 566. In addition, it held that when a "claim amendment" creates prosecution history estoppel regarding a "claim element," there is no range of equivalents available for the "amended claim element." *Id.* at 569. These new rules betray a myopic, and perhaps

[1] Pursuant to SUP. CT. R. 37.3.(a), letters of consent to filing this brief from counsel for the parties are on file with the Clerk of this Court. The undersigned counsel authored this brief and no person other than *amicus curiae* has made a monetary contribution towards its preparation.

uninformed, view of the prosecution process and a failure to appreciate how essential the doctrine of equivalents is to the incentive for innovation in this country, particularly in the academic and non-profit community.

A recent survey of 170 leading research universities and 29 related non-profit institutions, among which are many of our major teaching hospitals and research institutes, shows that in 1999 these institutions collectively contributed $25.1 billion or 93% of the total funds spent by this sector for research and development, and almost 20% of the total spent in this country.[2] *See* Lori Pressman, Chair and Editor, *Association of University Technology Management, Inc. Licensing Survey: FY 1999* (2000) (hereinafter 1999 *AUTM Survey*), Attachment E. App. at 3a-8a.[3] In addition, in just this one year these institutions: filed 8,413 patent applications with the United States Patent and Trademark Office ("PTO"); received 3,477 patents; and collected $791.2 million from licensing and other agreements for use of their patent rights. App. at 3a-8a.

In 1999, technology transfer from the academic and non-profit community to the private sector also "contributed over $40 billion in economic activity and supported more than 270,000 jobs.... In addition, business activity

[2] Selected information from AUTM copyrighted works is reprinted and cited herein with the authorization from AUTM.

[3] *Compare with* Raymond M. Wolfe, Project Officer and Principal Author, *Research and Development In Industry: 1998*, NSF 01-305, Division of Science Resource Studies, National Science Foundation (Oct. 2000) (hereinafter *R&D In Industry*) at 87, Table A-29 (reporting that $145.1 billion was spent by private industry on research and development); M. Marge Machen, Project Officer, *Academic Research and Development Expenditures: Fiscal Year 1999*, NSF 01-329, Division of Science Resources Studies, National Science Foundation (June 2001) (reporting that 597 universities and colleges and 17 federally funded centers in the United States spent approximately $27.4 billion for research and development activities in 1999).

associated with sales of [417 new] products [was] estimated to generate $5 billion in U.S. tax revenues at the federal, state, and local levels. . . . [M]ore than sixty percent. . . of [the 3,900 license and option] . . . agreements were made with small companies . . . well established as sources of job growth and economic development." 1999 *AUTM Survey* (Introductory Message From The President).

An overview of the nine-year period from 1991-1999, during which AUTM has conducted an annual survey, further evidences the dynamic engine of innovation that the majority decision in *Festo* needlessly has placed at great risk. During this period, research universities and related non-profit institutions collectively: spent $169,962,640,140 on research and development; filed 45,301 patent applications; were issued 15,996 patents; and received $4,082,074,536 from licensing and option agreements. App. at 1a-2a.

During a hearing that led to the passage of the Bayh-Dole Act, the United States Senate was advised by the American Council on Education, the largest association of colleges and universities in the United States, the Council on Governmental Relations of the National Association of Colleges and University Business Officers, the Society of University Patent Administrators, and the University of Wisconsin, Wisconsin Alumni Research Foundation, that:

> As a practical matter, . . . the greater need for the patent incentive lies primarily with universities and non-profit organizations, and small business. Technology transfer by universities and non-profits depends entirely on the underlying patent position, . . . [G]iven the fact that most university-generated inventions are embryonic in nature and require a great deal of development, and often are ahead of their time in the commercial sense . . . the *need for exclusivity* [is critical].

Patent Policy: Hearings Before the Subcomm. on Science, Technology, and Space of the Senate Comm. on Commerce, Science, and Transportation, 96th Cong., 1st Sess., 243 (July 23, 1979) (statement of Howard W. Bremer on S. 1215 "Science and Technology Research and Development Utilization Policy Act") (hereinafter Bremer Testimony) (emphasis added).

If the doctrine of equivalents can no longer be relied upon by research universities and related non-profit institutions to provide the requisite certainty of title and security for their discoveries and inventions, then the substantial benefits that the public has enjoyed from the transfer of some of our nation's most treasured intellectual property to the private sector will be substantially diminished.

For many years before her appointment to the United States Court of Appeals for the Federal Circuit, Judge Newman was a prominent patent counsel in the bar and private industry. In her separate opinion in *Festo* she invited *amicus* participation in this Court to demonstrate that the doctrine of equivalents has been essential in promoting innovation:

> The present patent law has supported a blossoming of technology-based industry in a competitive environment that is conspicuous for its entrepreneurial vigor. The balance among inventor, investor, competitor, and consumer, and the effect of the doctrine of equivalents on that balance, is not explored in the parties' briefs and had sparse *amicus* participation. . . . Although its influence is not easy to quantify, it is generally accepted that the doctrine contributes to an industrial policy that seeks to support technologic innovation.

Festo, 234 F.3d at 641 (Newman, J., concurring in part, dissenting in part).

Therefore, many of the leading research universities and non-profit institutions in the United States appear today as *amicus curiae* to assist this Court in understanding the important role that the application of the doctrine of equivalents has played in the birth and nurturing of this "technologic innovation" and promoting the "Progress of Science and the Useful Arts." U.S. CONST., Art. I, § 8, cl. 8.

SUMMARY OF ARGUMENT

Three years ago, the United States Court of Appeals for the Federal Circuit asked this Court "to speak to the death of . . . [the] doctrine [of equivalents]" for many of the same policy reasons advanced by the majority decision in *Festo*. On that occasion, this Court emphatically and unanimously replied: "We decline that invitation." *Warner-Jenkinson*, 520 U.S. at 21.

This Court once again should decline that invitation and reverse the judgment in *Festo* because it abandons over two hundred years of Anglo-American jurisprudence and undermines the Bayh-Dole Act, which was premised on the settled nature of the doctrine of equivalents and enacted to accelerate technology transfer from academic and non-profit institutions into the private sector.

The majority decision in *Festo* incorrectly assumes that all inventions are of equal value to the public. They are not. For this reason, federal courts historically have afforded protection under the doctrine of equivalents based on the "degree of the invention" or qualitative value of a patent to the public, by comparing the importance of newly-disclosed art within a field, and other factors relevant to the disclosures made to the public. This necessarily contextual analysis has provided a framework within which these variables can be

considered in a balanced manner, before a determination is made as to whether a non-identical product or use is an infringing one. Accordingly, this Court appropriately has precluded that inquiry in the past only in those situations where a claim element was specifically amended for the sole purpose of meeting the statutory requirements of novelty and non-obviousness, set forth in 35 U.S.C. §§ 102-103 (2001). *See Warner-Jenkinson*, 520 U.S. at 32.

This Court also has reminded lower federal courts that it is their responsibility to determine what constitutes a patent's "equivalent." *See Warner-Jenkinson*, 520 U.S. at 40. As to the weight to be accorded amendments made during prosecution, they were cautioned: "What *is* permissible for a court to explore is the reason (right or wrong) for the objection and the manner in which the amendment addressed and avoided the objection." *Id.* at 33 n.7 (emphasis in original). What this Court did not condone is the wholesale abdication of a federal court's responsibility to conduct an equivalence analysis or to embark on redefining property and attendant rights vested at the time of a patent's issuance, both of which the majority decision in *Festo* did.

Accordingly, this Court should reverse the judgment in *Festo* and uphold the long established principle of *stare decisis*, by reaffirming *Warner-Jenkinson* and thereby relieving the federal courts from having to confront the potentially divisive constitutional question of whether judicial actions are indeed exempt from the proscriptions of the Just Compensation Clause of the Fifth Amendment of the United States Constitution. Rather, this Court should defer to Congress to determine whether the public interest is best served by discarding the doctrine of equivalents in a time of such unprecedented innovation. *See Festo*, 234 F.3d at 630 (Newman, J., concurring in part, dissenting in part) ("policy aspects of technologic innovation, industrial growth, and competition . . . do not inhere in this Court's 'special expertise' in adjudication of patent disputes."); App. 1a-23a.

ARGUMENT

I. The Judgment In *Festo* Should Be Reversed Because It Abandons Over Two Centuries Of Anglo-American Jurisprudence Concerning The Doctrine Of Equivalents.

A. The Doctrine Of Equivalents Was Adopted From English Common Law To Provide Patent Owners With Comparable Protection Under U.S. Law.

At the height of the Industrial Revolution, when our nation was competing head-to-head with England as a principal trade rival, the Court unanimously adopted the doctrine of equivalents, from English common law, to provide patent owners with comparable protection under U.S. law.

In *Morley Sewing Machine Co.* v. *Lancaster*, 129 U.S. 263 (1889), the Court reviewed the heritage and application of this doctrine in England in a "case . . . before Vice Chancellor Wood, in 1863, . . . [who] said:

> When the thing is wholly novel, and one which has never been achieved before, the machine itself which is invented necessarily contains a great amount of novelty in all its parts and one looks very narrowly and very jealously upon any other machines for effecting the same object, to see whether or not they are merely colorable contrivances for evading that which has been before done."

Morley, 129 U.S. at 280 (quoting *Curtis* v. *Platt*, 3 Ch. Div. 135 (1863)).

The Court also referenced a unanimous decision of the English Court of Appeals that explained the policy behind this doctrine:

> [It] goes to the root of this case . . . that this is . . . a pioneer invention; and it is by the light of that . . . we ought to consider whether there have been variations or omissions, and additions, which prevent the machine which is complained of from being an infringement . . . With regard to the additions and omissions, it is obvious that additions may be an improvement, and that omissions may be an improvement; but the mere fact that there is an addition, or the mere fact that there is an omission, does not enable you to take the substance of the plaintiff's patent. The question is . . . whether what has been taken is the substance and essence of the invention.

Morley, 129 U.S. at 282 (quoting *Proctor* v. *Bennis*, 36 Ch. Div. 740 (1887)).

Federal courts were then advised that, henceforth, comparable protection would be provided under U.S. law, which would apply the doctrine of equivalents:

> [W]here an invention is one of primary character, and the . . . functions performed by the [invention] are, as a whole, entirely new, all subsequent inventions which employ substantially the same means to accomplish the same results are infringements, although the subsequent [inventions] may contain improvements in the separate mechanisms.

Morley, 129 U.S. at 273.

At that time, the Court primarily was concerned with protecting "breakthrough," "first-in-the-field" or "pioneer" patents,[4] although it authorized the federal courts also to afford discoveries and inventions of lesser import with some degree of protection:

> [The patentee] having been the first person who succeeded in producing an . . . [invention] is entitled to a liberal construction of . . . [a patent's] claims. . . . [The patentee] was not a mere improver upon a prior machine, which was capable of accomplishing the same result; in which case . . . [the] claims would properly receive a narrower interpretation. This principle is well settled in the patent law, both in this country and in England.

Morley, 129 U.S. at 273.

Several years later, when the Court specifically was asked whether "the doctrine of equivalents applied only to

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[4] In *Westinghouse* v. *Boyden Power Brake Co.*, 170 U.S. 537, 561-62 (1898), the Court described the characteristics of a "pioneer" patent and provided specific examples:

> To what liberality of construction these claims are entitled depends to a certain extent upon the character of the invention, and whether it is what is termed in ordinary parlance a 'pioneer.' This word, although used somewhat loosely, is commonly understood to denote a patent covering a function never before performed, a wholly novel device, or one of such novelty and importance as to mark a distinct step in the progress of the art, as distinguished from a mere improvement or perfection of what had gone before. Most conspicuous examples of such patents are: The one to Howe of the sewing machine; to Morse of the electrical telegraph; and to Bell of the telephone.

primary patents," it announced the rule of law under which all patents subsequently have been issued: "the range of equivalents depends upon the extent and nature of the invention. . . . It was not meant to decide that only pioneer patents are entitled to invoke the doctrine of equivalents, but it was decided that the range of equivalents depends and varies on the degree of invention." *Continental Paper Bag Co.* v. *Eastern Paper Bag Co.*, 210 U.S. 405, 414-15 (1908) (internal citations omitted).

B. The Range Of Protection Afforded Under The Doctrine Of Equivalents Has Been Determined By The Qualitative Value Of The Discovery Or Invention To The Public.

The range of protection afforded under the doctrine of equivalents has been determined by the "degree of invention," *i.e.*, the qualitative value of the discovery or invention to the public. Federal courts typically begin this analysis by comparing new art disclosed against existing and prior art in a field. *See, e.g.*, *Consolidated Roller-Mill Co.* v. *Barnard & Leas Mfg. Co.*, 156 U.S. 261, 269 (1894) (distinguishing, in an unanimous opinion, between a patent that "supercedes prior art [from a pioneer patent] . . . entitled to that liberality of construction which would have been accorded to it had [the invention] been the first to devise a scheme for these several adjustments."); *Cimiotti Unhairing Co.* v. *American Fur Refining Co.*, 198 U.S. 399, 406 (1905) ("In determining the construction to be given to the claim . . . it is necessary to have in mind the nature of this patent, its character as a pioneer invention or otherwise, and the state of art at the time when the invention was made.").

The potential benefit of a discovery or invention to the public also has been expressed in terms of its "work

component." [5] At one end of this spectrum are discoveries or inventions that disclose teachings of basic and higher level and more abstract applied research. These are of the "highest value" to the public because they are the essential building blocks in the "Progress of Science and the Useful Arts," even though their immediate prospect for commercialization may be remote. Accordingly, such patents have been afforded preferential treatment in the law, manifested by broad claim construction and comprehensive protection under the doctrine of equivalents to prevent infringers from exploiting their value by making trivial and insignificant changes that contribute nothing of substance to the process of transforming knowledge and bringing basic and applied research within the reach of commercial realization. *See, e.g., Eibel Process Co.* v. *Minnesota & Ontario Paper Co.*, 261 U.S. 45, 63 (1923); *Continental Paper Bag Co., supra*; *Boyden Power Brake, supra at* 573 (Shira, J., dissenting). [6]

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[5] The National Science Foundation characterizes research and development activities, based on their "work component," as defined by their benefit to the public, rather than sweat-of- the- brow: basic research; applied research; and development. *See R&D In Industry* at 1. Basic research is defined as "the pursuit of new scientific knowledge or understanding that does not have specific immediate commercial objectives, although in fields of interest or potential commercial interest." *Id.* at 178. Applied research is "investigation toward discovering new scientific knowledge that has specific commercial objectives with respect to products, processes, or services." *Id.* Development is "the systematic use of the knowledge or understanding gained from research directed towards the production of useful materials, devices, systems, or methods, including the design and development of prototypes and processes." *Id.*

[6] *See "Science and Technology Policy: Past and Prologue – A Companion to Science and Engineering Indicators – 2000,"* National Science Board, 2 (2000) (hereinafter *National Science Board Indicators 2000*) (emphasis in original) ("[T]echnologies that are likely to blossom in the 21st century recalls yesterday's basic research. History instructs that we cannot predict *which* discoveries or technologies will change the lives of future generations. Rather, fundamental science and engineering research presents long-term opportunities – a high risk investment with high payoffs.").

On the other hand, lesser degrees of protection have been afforded under the doctrine of equivalents depending on when an invention is disclosed in the development stage and whether commercialization already has been achieved. *See e.g., Boyden Power Brake Co., supra.*; Christina Y. Lai, *A Dysfunctional Formalism: How Modern Courts Are Undermining The Doctrine Of Equivalents*, 44 UCLA L. Rev. 2031, 2040-41 (1997) ("A pioneer invention lacks prior art and represents a large and risky investment by the inventor. Its reward should be commensurate to this risk. . . . By contrast, when the patented invention is itself an improvement in a crowded art . . . broad protection is not warranted. Development of an 'improvement' invention typically does not signify a major conceptual breakthrough and generally does not entail the same costs and risks as development of a pioneer [invention].").

A comparison of a patent's claims with art within its field or consideration of its "work component," however, are not the exclusive means to measure "the degree of invention" in an equivalence analysis. This Court has specifically endorsed consideration of other factors and provided federal courts with latitude to conduct a contextual analysis of the qualitative value of the discovery before determining whether infringement has occurred:

> [E]quivalenc[e] must be determined against the context of the patent, the prior art, and the particular circumstances of the case. Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum . . . [and may include] [c]onsideration . . . to the purpose for which an ingredient is used in a patent, the qualities it has when combined with other ingredients, and the function which it is intended to perform.

Warner-Jenkinson, 520 U.S. at 24-25 (quoting *Graver Tank & Mfg. Co.* v. *Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950)).

Thus, patents with the "highest value to the public," as well as those that "describ[e] a limited improvement in a crowded field," and all inventions between these two poles are afforded some degree of protection under the doctrine of equivalents, although the latter is entitled only to "a limited range of permissible equivalents." *Warner-Jenkinson*, 520 U.S. at 27 n.4.

None of these considerations, however, were afforded so much as a footnote in the majority decision in *Festo*, which fashioned indiscriminate and absolute rules that preclude federal courts from utilizing the doctrine of equivalents to determine whether non-literal infringement has occurred, without regard to a discovery or invention's contribution to the art within its field, "work component," or other factors relevant to a patent's qualitative value to the public. Instead, the record of the prosecution history regarding an amendment[7] is now the sole determinate of whether an invention may even be considered to be infringed under the doctrine of equivalents as a matter of law. This sleight of hand did not escape the attention of Circuit Court Judge Newman, who knew from her first-hand experience in private practice that: "It has been routine . . . for patent solicitors to initially present broad claims to an invention, in the expectation of honing the claims in interaction with the examiner. As very few patent applications traverse the PTO

[7] The *Festo* court held that "[w]hen no explanation for a claim amendment is established, no range of equivalents is available." *Festo*, 234 U.S. at 578. The court further held that the prosecution history must affirmatively establish that the amendment was not made for a patentability reason. *Festo*, 234 U.S. at 586. This has the effect of denying the doctrine of equivalents to patentees whenever the patentee did not meet this burden, which has been subsequently imposed on the patentee. Nor can this burden be met now since the file history is closed.

without amendment or argument, few issued patents will be free of the consequences of these changes in the law [advanced in the majority decision]." *Festo*, 234 F.3d at 638 (Newman, J., concurring in part, dissenting in part). Thus, as a practical matter, the majority decision in *Festo* denies almost all existing patent owners of the "safe harbor" provided by the doctrine of equivalents to protect their property from opportunistic infringers.

This Court was faithful to over two centuries of Anglo-American jurisprudence when it reminded the lower federal courts a few years ago of a continuing preference and "judicial recognition of so-called 'pioneer' patents," and reaffirmed the well-established rule that presumes non-literal infringement, as a matter of law, where there is "'equivalence' between the elements of the accused product or process, and the claimed elements of the patented invention." *Warner-Jenkinson*, 520 U.S. at 21 (quoting *Graver Tank*, 339 U.S. at 609). This Court also was faithful to principles of *stare decisis* when it restated the rule that: "What constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case." *Id.* at 26 (quoting *Graver Tank*, 339 U.S. at 609). Most importantly, this Court remained faithful to the constitutional objective of promoting the "Progress of Science and the Useful Arts" when it reaffirmed: "Our prior cases have consistently applied prosecution history estoppel only where claims have been amended for a limited set of reasons, and we see no substantial cause for requiring a more rigid rule invoking an estoppel regardless of the reasons for a change." *Id.* at 32.

The contextual analysis of equivalence has afforded research universities and related non-profit institutions with the certainty and security of title essential to justify the transfer of their technology into the private sector for the benefit of the public. *See National Science Board Indicators 2000* at 6 ("Research universities have become not only incubators of innovation, but also partners in developing and

commercializing products that generate income and hold value for other sectors of the Nation's economy."). Under the restrictive and regressive rules recently announced by the majority decision in *Festo*, the public should not assume that it will continue to receive these benefits in the future.

For these reasons, this Court should overrule the judgment in *Festo* and reaffirm *Warner-Jenkinson*.

II. The Judgment In *Festo* Should Be Reversed Because It Undermines The Bayh-Dole Act.

Universities and related non-profit institutions conduct a significant portion of all basic and applied research performed in the United States as an integral part of their educational mission. *See The Bayh-Dole Act: A Guide To The Law And Implementing Regulations*, Council On Governmental Relations (1999) (hereinafter *Council on Governmental Relations Report*) <http://www.cogr.edu/bayh-dole.html >. Until the enactment of the Bayh-Dole Act in 1980, however, most of this research was not made available to private industry or otherwise commercialized. Both the academic and private sector viewed the prospect of licensing technology from governmental agencies as being too susceptible to the winds of policy to convey certainty and security of title. *See, e.g.*, Bremer Testimony at 243.[8]

[8] In addition, prior to the Bayh-Dole Act, fewer than 5% of the 28,000 patents issued to federal agencies were licensed for commercial use, primarily because those seeking to utilize federally-owned patents faced numerous regulatory barriers that made commercial development difficult, if not impossible. *See Technology Transfer: Administration of the Bayh-Dole Act By Research Universities*, United States Government Accounting Office Report to the Senate Committee on the Judiciary and the House Committee on the Judiciary (May 1998) (hereinafter *1998 GAO Report*) at 2.

The Bayh-Dole Act was enacted in 1980 to radically "reform U. S. patent policy related to government-sponsored research," by allowing universities and related non-profit institutions to obtain title to inventions discovered with federal funds, if commercialization was pursued through licensing and other relationships, primarily with small U.S. businesses. *See 1998 GAO Report* at 3. By that time, the Court had settled that federal courts should apply the doctrine of equivalents in a contextual manner to prevent non-literal infringement. *See Graver Tanker*, *supra*. Accordingly, this doctrine was a necessary component to provide the certainty and security of title required by academic and non-profit institutions to transfer their patents to the private sector. In addition, it provided the necessary incentive for the business community to license such technology, rather than developing identical technology after having the opportunity to study academic and non-profit discoveries and inventions. *See, e.g., Industrial Innovation and Patent and Copyright Law Amendments: Hearings Before the House Subcomm. on Courts, Civil Liberties, and the Administration of Justice*, 96th Cong., 2nd Sess., 105 (April 15, 1980) (statement of Donald R. Dunner, President, American Patent Law Association on H.R. 6033, H.R. 6934, H.R. 3806, H.R. 214 (President's Industrial Innovation Program)) ("[B]usinessmen of ordinarily high ethics dishonor patents . . . and indulge in self-help of . . . infringement-plus-a-long-drawn-out litigation, [if they are] secure in the knowledge that courts . . . [will not] find infringement to be deliberate.").

Technology transfer from the academic and non-profit community to the private sector that followed as a result of these settled expectations has fueled an unprecedented period of technological innovation of widespread benefit to the public:

> [U]niversities and their researchers . . . benefit . . . because they . . . receive royalties on their inventions. The government and

> public . . . benefit . . . because more government-funded technology . . . [is] being brought to those . . . that [can] make use of it. . . . [U]niversities are increasing their licensing activities and . . . revenues from licenses are growing. . . . [A]ctivities involving inventions have added to the economy in general. [Although] [s]uccess with inventions and licensing varied widely among the universities . . . most of them had at least one notable invention.

1998 GAO Report at 15.

In addition, licensing fees and other revenues derived from technology transfer have become an increasingly important source of funding for research activities conducted at universities and related non-profit institutions in the United States. *Id.* at 2. Although such revenues are far from adequate independently to support all such research, they are nevertheless an important and growing supplement to federal funds to continue new patent issuance and in the creation of start-up companies to generate new products and revenues to fund another cycle of innovation. *Id.* at 4, 9-10, 13-15.[9] App. 1a-23a.

Thus, the certainty and security of title afforded research universities and related institutions by the twin pillars of the doctrine of equivalents and the Bayh-Dole Act has "protect[ed] the right of scientists to continue to use and to build on a specific line of inquiry. This is fundamentally important to research-intensive institutions because . . . [it] is

[9] *See National Science Board Indicators 2000* at 5 ("[I]n an $8.8 trillion knowledge-based economy... given the extraordinary contributions of fundamental research to long term economic growth, an investment greater than the 22 percent of the total Federal R&D budget that currently goes to 'basic research' more than seems justified.").

the only way of ensuring that the institution will be able to accept funding from interested research partners in the future. This is a critically important benefit of the Bayh-Dole Act that is not widely understood . . . [which has] led to breathtaking advances in the medical, engineering, chemical, computing and software industries, among others." *Council on Governmental Relations Report* at 9-10.

The majority decision in *Festo,* however, did not even consider the importance of the doctrine of equivalents in providing the certainty and security of title essential for academic and non-profit institutions to transfer their patented technologies to the private sector. Thus, "the majority's new rigid rule[s] will effect a serious invasion of the patentee's security of receiving the full benefits of his invention and [are] likely to be a disincentive to early disclosure of new inventions and discoveries." *See Festo*, 234 F.3d at 629 (Linn, J., concurring in part, dissenting in part, in which Rader, J., joins). Accordingly, the judgment in *Festo* should be reversed.

III. The Judgment In *Festo* Should Be Reversed To Relieve Federal Courts From Having To Resolve A Potentially Divisive Constitutional Question.

A. The Majority Decision in *Festo* Adversely Affects Vested Property Rights.

There has never been any dispute that intellectual property is protected under the Fifth Amendment. *See, e.g.*, U.S. CONST., Art. I, § 8, cl. 8 (Congress may secure "the exclusive Right to . . . Discoveries"); 35 U.S.C. § 261 (2001); FEDERALIST No. 43 (James Madison) ("The copyright of authors has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems with equal reason to belong to the inventors"); *see also Patent Policy: Hearings Before the Subcomm. on Science, Technology, and Space of the Senate Comm. on Commerce,*

Science, and Transportation, 96th Cong., 1st Sess., 281 (July 27, 1979) (statement of Tom Arnold, President, American Patent Law Association on S. 1215 "Science and Technology Research and Development Utilization Policy Act") ("The Constitution and the patent statute promised to the inventor . . . title to [the] invention, as it were, a piece of property.").

Property law delineates the boundaries of ownership; the right to exclude others from using property, however, is derived from the common law tort of trespass. Similarly, a patent's claims define the boundaries of ownership; but the right to preclude equivalent infringement is derived from the common law doctrine of equivalents. Thus, it has long been accepted that property and attendant rights in an invention include both what a patent's claims disclose and their substantial equivalent: "[Th]e thing entitled to protection . . . [is the "new mode" and] to copy the principle or mode of operation described, is an infringement, although such copy should be totally unlike the original in form or proportion . . . inventors [should] retain to their own use . . . what they themselves have created." *Winans* v. *Denmead*, 56 U.S. 330, 341-42 (1853). In short, the doctrine of equivalents focuses on what an inventor created as well as the language used to describe it. *See* Kurt L. Giltzenstein, *A Normative and Positive Analysis of the Scope of the Doctrine of Equivalents*, 7 Harv. J. Law & Tech. 281, 302 (1994).

By no longer affording a patent owner protection from insubstantial or colorable deviation or imitation, the majority decision in *Festo* adversely affects property rights vested at the time of patent issuance.

B. The Majority Decision In *Festo* Effects A Taking of Property.

In exchange for and in consideration of the disclosure of a trade secret describing a discovery or invention that advances the "Progress of Science and Useful Arts,"

Congress authorized the PTO to convey to the inventor for a "limited time" the privilege of a "public franchise . . . the exclusive right and liberty to make and use and vend to others [property and attendant rights] to be used as their own inventions[.]" *Seymour* v. *Osborne*, 78 U.S. 516, 533 (1870). The franchise covers both a discovery or invention, as well as its equivalent. *See Winans*, 56 U.S. at 342. The majority decision in *Festo*, however, substantially changes the terms of this franchise.

First, the scope of the patent is narrowed by requiring federal courts to invoke prosecution history estoppel whenever "a narrowing amendment [is] made for any reason related to the statutory requirements for a patent[.]" *Festo*, 234 F.3d at 566. Since almost all patents are amended during prosecution, however, an owner's ability to protect its property from non-literal infringement is only ephemeral at best. *See, e.g., Festo*, 234 F.3d at 638 (Newman, J., concurring in part, dissenting in part); Brief of *Amicus Curiae* of the Chamber of Commerce of the United States, *Festo* v. *Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, On Petition For Writ Of Certiorari (No. 00-1543) at 7 ("The value of a patent is inextricably linked to the patent owner's ability to enforce it. When the scope of enforcement rights is substantially narrowed, the value of patent portfolio assets is substantially diminished.").[10]

Second, the retroactive application of the majority decision in *Festo* precludes owners from receiving the full benefit of rights vested at issuance for the entire term of the

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[10] *See, e.g., Mycogen Plant Science, Inc.* v. *Monsanto Co.*, 252 F.3d 1306 (Fed. Cir. 2001) (holding under *Festo* that prosecution history estoppel barred application of the doctrine of equivalents to all claims where the PTO examiner rejected a claim for indefiniteness and lack of enablement, even though that claim was replaced by limiting language acceptable to the examiner).

patent.[11] This will have a significant adverse impact on academic and non-profit institutions that actively license their patent technology. As a result of the new patent rights secured by the Bayh-Dole Act and protections afforded under the doctrine of equivalents, research universities in the United States received gross income in excess of $641 million in 1999. App. 7a. Related non-profit institutions, such as U.S. hospitals and research institutes, received an additional $16.4 million. App. at 8a. Although these licensing agreements generally run for the full term of the patent, many will be abrogated if the judgment in *Festo* is not overruled. *See Warner-Jenkinson*, 520 U.S. at 32 (determining that it would be improper to "change so substantially the rules of the game now [and] subvert to the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision").

Thus, to the extent that research universities and related non-profit institutions are denied the financial benefit of the full term of their current licensing agreements, the majority decision in *Festo* will affect a taking of property, as Circuit Judge Michel recognized:

> [T]he majority's new rule, far from providing patentees the protections the Supreme Court has guaranteed, unfairly strips most patentees of the right to assert infringement under the doctrine of equivalents . . . [and] might most directly impact untold numbers of licensing agreements that are predicated on the assumption that patent claims with an amended limitation are still entitled to a

[11] *See* 35 U.S.C. § 154(a)(2), P.L. 103-465; § 532(a)(1) 108 Stat. 4983 (Dec. 8, 1994) (changing the term of a patent from 17 years from issuance to 20 years from filing).

> range of equivalents. Licensees will be tempted to exploit today's ruling. . . . A licensee could make a minor substitution of a known interchangeable element for an amended claim limitation, and then correctly claim that it is no longer practicing the patented -- and licensed -- invention. The licensor would then be powerless to enforce the license because the amended claim or claims simply would not cover the licensee's newly-modified product or process. . . . [T]oday's ruling will upset basic assumptions regarding the effective scope of patents, and will unfairly disrupt commercial relations based on these assumptions[.]

Festo, 234 F.3d at 616, 619 (Michel, J., concurring in part, dissenting in part, with whom Rader, J., joins).

Just two months ago, this Court in *Palazzolo* v. *Rhode Island*, 121 S. Ct. 2448, 2463 (2001), reaffirmed that where the government imposes a rule that "would work a critical alteration to the nature of property . . . the State may not by this means secure a windfall for itself." *See, e.g., Webb's Fabulous Pharmacies, Inc.* v. *Beckwith*, 449 U.S. 155, 164 (1980) ("[A] state, by *ipse dixit*, may not transform private property into public property without compensation."). If patent owners are denied the financial benefit of the full scope of their patents, a taking will be effected because the public already has received the benefit of the disclosure.

In her separate concurring opinion, Justice O'Connor also reminded the lower courts that:

> [W]e have eschewed "any 'set formula' for determining when 'justice and fairness' require that economic injuries caused by public action be compensated by the government, rather than remain

> disproportionately concentrated on a few persons." The outcome instead "depends largely 'upon the particular circumstances.'" . . . Evaluation of the degree of interference with investment-backed expectations instead is one factor that points toward the answer to the question whether the application of a particular [rule] to particular property "goes too far."

Palazzolo, 121 S. Ct. at 2466 (O'Connor, J., concurring) (quotations in original and internal citations omitted). Thus, although investment-backed expectations are not determinative of whether a taking has occurred, nevertheless, they are important in takings analysis and, in the instant case, a compelling factor.

The view that property law may be changed by the courts at will and made prospective, as the Court held in *Great Northern Railway Co.* v. *Sunburst Oil & Refining Co.*, 287 U.S. 358 (1932), conflicts with earlier decisions of the Court[12] and has been eroded by more recent decisions. *See, e.g.*, *General Motors Corp.* v. *Romein*, 503 U.S. 181, 191 (1992) (retroactive application of the law presents constitutional problems "because it can deprive citizens of legitimate expectations and upset settled transactions."); *Eastern Enterprises* v. *Apfel*, 524 U.S. 498, 528-29 (1998) (O'Connor, J., plurality opinion) (governmental action "might be unconstitutional [as a taking] if it imposes severe retroactive liability on a limited class of parties that could not

[12] *See, e.g., Chicago, Burlington & Quincy Railroad* v. *City of Chicago*, 166 U.S. 226, 233-35 (1897) (holding that the protections of the "Just Compensation" Clause apply to judicial action); *Muhlker* v. *New York & Harlem Railroad Co.*, 197 U.S. 544, 568 (1905) (McKenna, J., plurality opinion) (observing that courts should not be allowed to strip owners of property rights by overruling prior precedent).

have anticipated the liability, and the extent of that liability is substantially disproportionate to the parties experience.").[13]

By reversing the judgment in *Festo*, this Court will relieve federal courts from having to resolve a potentially divisive constitutional question regarding the "Just Compensation Clause" of the Fifth Amendment. *See* Barton H. Thompson, Jr., *Judicial Takings*, 76 Va. L. Rev. 1449 (1990) ("[T]here is no justification for exempting the judiciary from those property protections that are necessary where other branches of government are concerned . . . in ways relevant to takings protections, courts are not always substantially different from the other branches of government.").

IV. The Judgment In *Festo* Should Be Reversed Because Congress Is The Proper Forum To Resolve Policy Differences Concerning Patent Law.

This Court clearly recognizes that "Congress can legislate the doctrine of equivalents out of existence any time it chooses . . . policy arguments . . . are thus best addressed to Congress, not this Court." *Warner-Jenkinson*, 520 U.S. at 28. The majority decision in *Festo*, however, is the result of distinct policy preferences and untested assumptions: "[U]nder the complete bar approach, technological advances that would have lain in the unknown, undefined zone around the literal terms of a narrowed claim under the flexible bar approach will not go unwasted and undeveloped due to fear of litigation. . . . This certainly will stimulate investment in

[13] Moreover, in light of the fact that there is nothing a patent owner can now do today to avoid application of the strict rule advanced by the majority decision in *Festo*, it also offends constitutionally protected notions of fairness. *See Eastern Enterprises*, 524 U.S. at 549 (Kennedy, J., concurring in part, dissenting in part) (the "degree of retroactive effect" is a "significant determinant in assessing constitutionality [under the Due Process Clause].").

improvements and design-around because the risk of infringement will be easier to determine." *Festo*, 234 F.3d at 577.

The speculative benefits to be gained by eviscerating the doctrine of equivalents, according to the majority decision in *Festo,* however, stand in stark contrast to the public record evidencing the dramatic rise in technological advance and economic stimulus made possible by the time-tested application of that doctrine:

- Annually $30 billion of economic activity is generated from the commercialization of new technologies from academic institutions, supporting 250,000 jobs and creating over 2,200 new companies since 1980.

- 70% of the active licenses from research university patent and licensing efforts are in life –sciences, including: artificial lung surfactant used by newborn infants; cisplatin and carboplatin cancer therapeutics; Citracal® calcium supplements; Haemopohilus B conjugate vaccine; metal alkoxide process for taxol production; Neuprogen® used with chemotherapy; the process for inserting DNA into eucaryotic cells and for producing proteinacous materials; recombinant DNA technology, central to the biotechnology industry; and TRUSOPT® (dorzolmide) opthalmic drops used by glaucoma patients -- just to name a few.

See Council on Governmental Relations Report at 8.

This innovation took place in an environment where the law was settled. Yet, the majority decision in *Festo* concludes that the "state of the law regarding the scope of equivalents . . . is . . . 'unworkable,'" without an *iota* of

empirical evidence evidencing how that is so. *See Festo*, 234 F.3d at 575.

Federal courts often are required to conduct a contextual analysis in other fields of law, including those concerning intellectual property. For example, "fair use" and "substantial similarity" determinations in copyright require federal courts to weigh and balance a number of factors in determining whether infringement has occurred. *See, e.g., Harper & Row, Publishers, Inc.* v. *Nation Enterprises*, 471 U.S. 539, 560 (1985) (holding that fair use must be determined on a case-by-case basis and is not susceptible to a single, uniform definition "since the doctrine is an equitable rule . . . each case raising the question must be decided on its own facts."); *Computer Assoc. Int'l, Inc.* v. *Altai, Inc.*, 982 F.2d 693 (2d Cir. 1992) (Walker, J.) (applying an "abstraction-filtration-comparison" test to determine whether there was non-literal infringement of a computer software program). The majority decision in *Festo* suggests no reason why federal courts are unable to conduct a similar contextual case-by-case analysis to determine whether non-literal infringement has occurred in patent infringement cases, other than the simplicity that a "bright line standard" offers imitators, at the expense of genuine innovators.

This Court should know that the adverse impact of the rigid rule in *Festo* disproportionately will fall on *amici curiae*, because their research and development activities are inherently more oriented to basic and applied research where patent claims necessarily are drafted broadly given the dearth of prior art and then narrowed during prosecution, as the examiner becomes more comfortable with the nature of the discovery or invention. Thus, as Circuit Court Judge Linn warns, "[T]he majority's new bright line rule, . . . [will tend to limit amendments] for a statutory purpose to their literal terms. This is likely to encourage insubstantial changes to an established product, rather than investment in break-through technological advances." *Festo*, 234 F.3d at 627 (Linn, J., concurring in part, dissenting in part, in which Rader, J.,

joins). This is, of course, contrary to the majority's reasoning that limiting the doctrine of equivalents only for patents issued without amendments will encourage so-called "inventing around." To the contrary, it will only encourage insubstantial changes or minor improvements over prior art that will do little to promote the "Progress of Science and the Useful Arts." U.S. CONST. Art. I, § 8, cl. 8. In this respect, the majority decision in *Festo* imitates Japanese patent law, departing from the moorings of over 200 years of Anglo-American jurisprudence.[14] Whether U.S. patent law should be harmonized in this manner clearly should be left for Congress to determine, not the federal judiciary.

In 1980, the Congress considered the question: "[I]n whose hands will the vestiture of primary rights to an invention serve to transfer the inventive technology most quickly to the public for its use and benefit?" *See* Bremer Testimony at 240. Congress answered that question by enacting the Bayh-Dole Act, which this Court should not undermine by reducing the protections afforded U.S. patent owners under the doctrine of equivalents, unless and until Congress advises this Court otherwise.

For these reasons, the judgment in *Festo* should be overruled.

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[14] *See* Nancy J. Linck and John E. McGarry, *Patent Procurement and Enforcement in Japan – A Trade Barrier*, 27 GW J. Int'l L. & Econ. 411 (1993-1994) ("[T]he U.S. legal system rewards entrepreneurs and innovators through the grant of exclusive rights to implement their inventions for limited periods of time. In contrast, . . . the Japanese legal system promotes the sharing of technology among competitors and discourages patent litigation. . . . Hence the Japanese patent system is biased towards small incremental improvements and is typically biased against the patenting of pioneer inventions . . .which are usually technologically important." *Id.* at 413-14, 418. "The Japanese Patent Office tends to limit applications to demonstrated improvements and to a scope of protection determined by specific disclosed examples or factors. Japanese courts accordingly enforce this limitation." *Id.* at 414.) (Ms. Linck formerly was the Solicitor of the PTO).

CONCLUSION

This Court should reverse the judgment in *Festo* and once again affirm the continued vitality of the doctrine of equivalents.

Respectfully submitted,

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Association of University Technology Managers, Inc. Licensing Survey: FY 1991-1999
Summary Chart of Selected Data From U.S. Universities

U.S. UNIVERSITIES:								
Year	FY 1991-1999 Total Sponsored Research Expenditures	FY 1991-1999 Invention Disclosures Received	FY 1991-1999 Total U.S. Patent Applications Filed	FY 1991-1999 U.S. Patents Issued	FY 1991-1999 Licenses & Options Yielding License Income	FY 1991-1999 Licenses & Options Executed	FY 1991-1999 Adjusted (*) Gross License Income Received	FY 1991-1999 Start-up Companies Formed
1991	$11,479,381,778	4,880	1,926	NA	2,210	1,079	$129,981,898	NA
1992	12,799,045,236	5,700	2,339	NA	2,809	1,461	172,359,459	NA
1993	14,875,677,330	6,598	3,099	1,307	3,413	1,737	242,269,815	NA
1994	16,058,664,323	6,697	3,477	1,596	3,560	2,049	265,932,578	NA
1995	17,211,913,185	7,427	5,100	1,550	4,272	2,142	299,148,128	NA
1996	18,688,253,796	8,119	3,872	1,776	4,958	2,209	365,218,642	184
1997	19,858,137,796	9,051	5,591	2,239	5,659	2,707	482,793,071	258
1998	21,386,650,472	9,555	6,518	2,681	6,006	3,078	576,889,538	279
1999	23,565,568,068	10,052	7,612	3,079	6,663	3,295	641,000,108	275
TOTALS:	**$155,923,291,976**	**68,071**	**39,526**	**14,228**	**39,542**	**19,749**	**$3,175,593,237**	**996**

Association of University Technology Managers, Inc. Licensing Survey: FY 1991-1999
Summary Chart of Selected Data From U.S. Hospitals & Research Institutes

U.S. HOSPITALS & RESEARCH INSTITUTES:								
Year	FY 1991-1999 Total Sponsored Research Expenditures	FY 1991-1999 Invention Disclosures Received	FY 1991-1999 Total U.S. Patent Applications Filed	FY 1991-1999 U.S. Patents Issued	FY 1991-1999 Licenses & Options Yielding License Income	FY 1991-1999 Licenses & Options Executed	FY 1991-1999 Adjusted (*) Gross License Income Received	FY 1991-1999 Start-up Companies Formed
1991	$802,177,881	472	416	NA	268	119	$45,255,639	NA
1992	902,266,306	577	438	NA	315	192	60,233,269	NA
1993	1,507,164,756	772	539	173	409	252	73,969,108	NA
1994	1,465,486,884	749	575	168	491	211	85,560,310	NA
1995	1,749,635,279	974	952	146	586	247	116,740,155	NA
1996	1,867,573,130	860	578	199	676	279	135,037,920	15
1997	1,771,914,820	987	690	277	735	361	129,322,500	16
1998	1,862,171,661	965	794	407	828	316	110,213,653	26
1999	2,110,957,455	1,106	801	398	957	355	150,148,745	17
TOTALS:	**$14,039,348,164**	**7,454**	**5,775**	**1,768**	**5,257**	**2,324**	**$906,481,299**	**74**

Association of University Technology Managers, Inc. Licensing Survey: FY 1999

U.S. UNIVERSITIES:

Name of Institution	FY 1999 Total Sponsored Research Expenditures	FY 1999 Invention Disclosures Received	FY 1999 Total U.S. Patent Applications Filed	FY 1999 U.S. Patents Issued	FY 1999 Licenses & Options Yielding License Income	FY 1999 Licenses & Options Executed	FY 1999 Adjusted (*) Gross License Income Received	FY 1999 Start-up Companies Formed
University of California Systems	$1,864,901,000	818	670	281	715	219	$74,133,000	13
Johns Hopkins University	$1,010,088,334	250	256	111	137	106	$10,353,453	7
Massachusetts Inst. of Technology (MIT)	$725,600,000	381	341	154	346	95	$16,131,334	17
Univ. of Michigan	$499,722,000	158	147	56	90	42	$3,472,671	2
Univ. of Washington/Wash. Res. Fndtn.	$479,654,994	226	114	36	185	115	$27,878,900	NA
Univ. of Pennsylvania	$477,000,000	244	151	82	55	57	$2,984,000	6
W.A.R.F./Univ. of Wisconsin-Madison	$421,600,000	278	162	79	191	106	$18,011,400	4
Univ. of Minnesota	$417,556,493	219	99	55	153	71	$5,662,088	5
Stanford University	$417,037,000	236	237	90	339	147	$27,699,355	19
North Carolina State University	$413,369,278	148	62	30	60	83	$7,761,000	8
SUNY Research Foundation	$405,238,284	201	123	53	149	46	$13,538,619	3
Texas A&M University System	$402,203,000	145	85	19	155	53	$5,180,510	0
Harvard University	$401,849,500	109	186	72	166	48	$9,886,404	2
Penn State University	$393,462,000	188	231	46	64	40	$2,830,448	3
Cornell Research Fndtn., Inc.	$376,784,000	172	147	70	199	150	$6,070,000	4
Univ. of Illinois, Urbana, Champaign	$358,247,000	104	53	14	84	39	$2,856,207	4
Duke University	$334,505,814	115	111	43	73	41	$1,566,195	2
Washington University	$333,196,000	104	78	39	107	114	$6,999,971	4
Univ. of Colorado	$331,579,000	79	63	27	10	10	$3,127,303	1
Univ. of Arizona	$320,244,777	97	40	8	31	11	$314,299	3
Yale University	$315,953,000	70	110	37	28	23	$40,695,606	3
Univ. of Pittsburgh	$311,200,000	107	70	30	23	16	$608,851	3
Univ. of Florida	$280,408,217	136	127	58	45	10	$21,649,577	2
Columbia University	$279,275,674	182	109	77	212	98	$89,159,556	5
Univ. of Iowa Research Fndtn.	$259,514,262	79	83	32	80	21	$3,464,565	2
Univ. of Texas at Austin	$258,122,000	81	49	17	24	31	$1,929,390	1
Ohio State University	$257,950,000	100	35	18	34	26	$1,626,000	0
Univ. of Southern California	$254,811,651	156	101	13	55	57	$450,568	4
Purdue Research Foundation	$253,018,364	102	81	24	201	76	$2,149,000	4
Baylor College of Medicine	$239,000,000	89	39	25	110	35	$12,280,879	0
Univ. of Georgia	$237,493,000	72	44	21	64	32	$3,208,427	5
Northwestern University	$236,668,615	80	71	35	38	14	$2,758,450	0

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U.S. UNIVERSITIES:

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Georgia Institute of Technology	$223,641,675	127	143	23	46	18	$2,038,078	3
Univ. of Missouri System	$212,238,803	62	37	22	21	16	$1,544,985	1
Indiana University (ARTI)	$209,154,093	59	38	18	39	14	$1,040,092	1
Michigan State University	$207,912,000	85	82	63	48	33	$23,711,867	1
Univ. of Massachusetts, All Campuses	$206,382,231	112	NA	32	41	19	$4,105,000	2
Emory University	$205,600,000	89	50	44	35	13	$15,257,565	4
Univ. of North Carolina/Chapel Hill	$198,081,333	116	74	41	47	70	$1,696,786	0
Univ. of Virginia Patents Fndtn.	$197,046,500	154	155	23	62	25	$4,185,446	6
Iowa State University	$186,700,000	160	106	49	298	163	$1,812,870	2
Univ. of Rochester	$185,488,000	85	53	14	17	5	$2,994,170	1
Univ. of Maryland, College Park	$185,036,200	84	113	12	109	61	$968,144	3
Univ. of Utah	$182,753,466	172	98	40	58	25	$3,257,026	8
Univ. of Texas Southwestern Med. Ctr.	$179,709,069	80	63	27	57	23	$4,856,751	1
Case Western Reserve University	$176,519,336	59	37	17	16	10	$505,192	3
Univ. of Miami	$175,600,000	27	9	8	22	9	$432,937	0
Univ. of Illinois at Chicago	$175,093,000	61	35	13	45	20	$1,839,290	2
Univ. of Alabama/Birmingham	$171,831,840	121	113	24	58	40	$1,560,587	2
Univ. of Tennessee Research Corp.	$170,896,000	75	54	17	24	7	$602,053	1
Virginia Tech Intellectual Properties, Inc.	$169,250,000	65	58	37	74	41	$1,328,343	3
Carnegie Mellon University	$167,675,342	104	36	30	51	23	$5,892,284	5
Univ. of Kansas	$167,575,000	67	22	10	39	7	$885,000	1
Rutgers, The State University of NJ	$165,872,573	112	103	31	73	60	$4,304,616	3
Vanderbilt University	$165,200,000	87	51	17	44	31	$1,100,579	2
Univ. of Chicago-ARCH Dev. Corp.	$162,805,000	65	74	33	40	14	$1,868,392	1
Univ. of South Florida	$161,300,000	48	53	24	18	13	$490,408	8
Univ. of Hawaii	$151,809,406	41	36	11	19	0	$171,877	0
California Institute of Technology	$150,000,000	143	212	62	35	21	$6,500,000	6
New York University	$149,000,000	50	NA	30	18	NA	$10,700,000	2
Univ. of New Mexico/Sci. & Tech. Corp.	$148,600,000	47	53	15	9	3	$400,200	2
Colorado State University	$147,664,283	30	17	13	18	9	$386,990	4
Wayne State University	$147,000,000	39	18	18	12	3	$458,000	1
Oregon State University	$145,665,138	38	25	6	45	17	$825,283	1
Boston University	$142,515,956	56	52	22	18	17	$263,095	7

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Florida State University	$132,664,855	23	15	5	14	8	$57,313,014	1
Univ. of Maryland, Baltimore	$131,484,606	62	44	12	16	7	$116,681	2
Univ. of Nebraska-Lincoln	$131,046,000	32	28	9	24	8	$796,894	2
Mount Sinai School of Medicine of NYU	$123,404,735	36	35	9	14	12	$1,012,061	0
Univ. of Cincinnati	$115,025,000	47	36	6	16	15	$3,905,945	4
Virginia Commonwealth University	$113,000,000	88	68	14	21	17	$459,200	3
Univ. of Texas Houston Hlth. Sci. Ctr.	$107,035,788	20	12	6	9	8	$343,050	0
Univ. of Connecticut	$105,800,000	45	32	11	10	12	$481,134	2
Princeton University	$102,000,000	60	61	26	20	14	$1,480,000	2
Clemson University	$99,340,766	29	7	2	10	7	$4,648,141	1
Tufts University	$98,567,533	51	32	11	21	12	$506,149	0
Oklahoma State University	$88,900,000	19	9	4	7	1	$154,946	0
Tulane University	$87,324,000	13	17	7	19	9	$7,572,483	0
Oregon Health Sciences University	$86,822,525	32	45	15	32	11	$291,131	1
Univ. of Oklahoma-All Campuses	$85,584,836	30	45	8	7	6	$110,265	2
Thomas Jefferson University	$85,400,000	87	80	27	24	17	$742,515	1
Univ. of Texas Medical Branch	$85,000,000	30	38	21	10	4	$108,857	0
Univ. of Kentucky Research Fndtn.	$83,743,077	65	32	24	NA	9	$2,496,786	2
Medical Univ. of South Carolina	$81,246,129	40	24	8	11	5	$121,627	3
Dartmouth College	$81,055,083	18	26	20	47	7	$491,302	0
Auburn University	$80,544,000	25	13	12	6	5	$186,738	0
Utah State University	$80,539,784	27	7	6	15	4	$227,929	1
Univ. of Texas Hlth Sci Ctr San Antonio	$80,020,875	21	41	13	32	14	$3,660,638	0
Wake Forest University	$78,351,866	36	19	3	9	6	$2,788,987	1
Brown University Research Fndtn.	$76,330,000	40	36	17	13	4	$1,009,516	1
Univ. of South Carolina	$69,819,000	36	26	4	12	7	$175,187	0
Univ. of Delaware	$64,872,678	20	29	3	8	4	$470,303	2
Univ. of Arkansas, Fayetteville	$63,110,717	26	21	13	21	2	$259,883	1
New Mexico State University	$63,037,606	12	10	2	3	3	$1,792	0
West Virginia University	$62,000,000	9	3	2	5	1	$41,800	0
Arizona State University	$60,091,584	49	47	12	18	11	$1,274,145	1
Univ. of New Hampshire	$60,015,544	6	5	0	5	6	$34,696	0
Univ. of Oregon	$58,616,598	9	11	5	20	10	$232,000	1

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Univ. of Louisville	$53,258,000	30	9	2	4	3	$48,632	1
Kansas State University Research Fndtn.	$52,597,214	28	16	12	31	7	$258,063	2
Univ. of Vermont	$52,500,000	25	11	2	3	6	$338,000	0
Idaho Research Fndtn./Univ. of Idaho	$50,345,178	18	7	3	6	2	$140,500	0
Montana State University	$49,741,400	15	12	7	18	7	$243,700	1
Temple University	$45,456,670	19	NA	NA	16	5	$493,947	0
North Dakota State University	$44,696,000	23	6	4	38	7	$1,059,797	0
Rice University	$44,500,000	20	33	1	4	8	$21,000	1
Louisiana State University, Agric. Ctr.	$44,318,252	17	7	3	17	7	$1,091,787	1
Univ. of North Dakota	$43,131,073	2	1	0	0	0	$0	0
Brandeis University	$42,666,882	17	18	9	21	6	$120,126	3
New Jersey Institute of Technology	$42,500,000	35	8	4	3	2	$22,500	0
Univ. of Houston	$42,002,331	40	7	5	8	5	$120,831	0
Univ. of Maine	$41,453,000	6	3	4	0	2	$0	0
Univ. of Rhode Island	$41,400,000	12	7	3	10	11	$823,385	0
San Diego State University	$40,624,000	7	3	1	2	4	$82,000	2
Syracuse University	$39,500,000	10	4	5	16	1	$112,529	0
Univ. of Dayton	$37,039,132	28	9	8	5	2	$567,535	1
George Mason University	$32,376,000	13	11	3	1	0	$753	0
Loyola University Medical Center	$29,778,103	4	3	0	10	10	$567,500	0
Michigan Technological University	$28,073,860	20	11	2	18	11	$222,272	0
St. Louis University	$27,817,000	19	15	6	22	3	$788,472	0
Univ. of South Alabama	$27,252,916	5	11	6	3	0	$7,178	0
Creighton University	$25,700,000	17	3	2	4	2	$123,717	0
Lehigh University	$25,312,458	NA	NA	NA	7	NA	$117,661	NA
Southern Illinois Univ./Carbondale	$23,655,654	15	6	NA	9	6	$48,245	0
Kent State University	$23,472,249	12	5	4	7	3	$147,159	1
Univ. of Montana	$22,996,357	5	2	2	4	3	$67,000	0
New York Medical College	$22,821,758	16	3	3	8	3	$87,589	2
Wright State University	$22,753,000	2	1	1	6	4	$18,525	0
Univ. of New Orleans	$22,297,000	6	6	2	2	1	$13,770	0
Univ. of Maryland, Baltimore County	$21,854,000	26	9	6	2	1	$39,117	0
Univ. of Maryland Biotech Institute	$20,387,312	17	14	4	2	4	$335,000	0

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U.S. UNIVERSITIES:

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Brigham Young University	$17,226,876	71	12	4	51	21	$3,961,971	1
Ohio University	$16,492,896	13	8	4	3	0	$617,805	0
Univ. of Northern Iowa	$13,148,015	0	2	2	1	0	$1,268	0
Medical College of Ohio	$11,895,179	7	2	6	6	0	$22,991	0
Portland State University	$11,735,117	3	0	0	0	0	$0	0
California State Polytechnic University	$11,575,000	1	2	1	2	2	$10,000	0
Univ. of Akron	$10,193,500	29	20	11	15	7	$244,056	1
East Carolina University	$8,360,000	10	6	2	0	1	$76,000	0
TOTALS:	**$23,565,568,068**	**10,052**	**7,612**	**3,079**	**6,663**	**3,295**	**$641,000,108**	**275**

Association of University Technology Managers, Inc. Licensing Survey: FY 1999

U.S. HOSPITALS AND RESEARCH INSTITUTES: Name of Institution	FY 1999 Total Sponsored Research Expenditures	FY 1999 Invention Disclosures Received	FY 1999 Total U.S. Patent Applications Filed	FY 1999 U.S. Patents Issued	FY 1999 Licenses & Options Yielding License Income	FY 1999 Licenses & Options Executed	FY 1999 Adjusted (*) Gross License Income Received	FY 1999 Start-up Companies Formed
Massachusetts General Hospital	$247,034,000	174	170	85	60	40	$6,603,343	4
Mayo Foundation	$240,500,000	119	72	31	124	31	$4,361,548	0
Brigham & Women's Hospital	$196,289,000	81	70	26	70	28	$3,149,675	4
M.D. Anderson Cancer Center	$155,126,396	67	36	20	60	17	$3,169,420	0
Fred Hutchinson Cancer Res. Ctr.	$141,372,000	26	12	14	75	21	$2,103,483	2
Beth Israel Deaconess Medical Ctr.	$117,327,557	63	41	29	32	21	$1,171,033	3
Sloan Kettering Institute for Cancer Res.	$100,982,132	36	24	7	44	22	$43,065,502	1
Dana-Farber Cancer Institute	$94,477,120	47	22	33	65	21	$2,268,182	0
Children's Hospital, Boston	$85,000,000	75	82	27	30	13	$2,616,923	1
Health Research, Inc.	$75,800,000	19	7	14	35	7	$6,996,742	0
St. Jude Children's Research Hospital	$73,778,337	32	16	6	43	16	$619,921	0
Medical College of Wisconsin	$72,500,000	10	6	3	20	9	$469,265	1
City of Hope National Medical Ctr.	$65,890,000	40	31	10	24	0	$23,752,074	0
Woods Hole Oceanographic Inst.	$62,118,319	1	0	0	2	0	$118,300	0
Children's Hospital of Philadelphia	$58,348,000	21	15	2	7	4	$101,160	0
Children's Hospital, Cincinnati	$55,419,771	20	12	2	9	3	$315,459	0
Fox Chase Cancer Center	$54,242,489	31	23	2	26	37	$331,676	1
Salk Institute	$51,416,000	45	38	21	68	23	$2,521,687	0
National Jewish Med. And Res. Ctr.	$34,234,123	9	12	7	18	3	$510,864	0
Wistar Institute	$23,974,000	10	33	7	53	15	$2,482,000	0
Oklahoma Medical Research Fndtn	$23,777,502	17	19	5	20	2	$586,988	0
Hospital for Special Surgery	$18,515,000	8	5	2	9	0	$5,587,603	0
Institute of Paper Science and Tech.	$15,599,000	17	11	4	0	2	$0	0
New York Blood Center	$14,000,000	9	NA	14	30	6	$35,000,000	0
California Pacific Medical Ctr. Res. Inst.	$12,751,706	4	1	0	0	0	$0	0
Schepens Eye Research Institute	$10,599,003	6	7	3	3	0	$125,375	0
Torrey Pines Inst. For Molecular Studies	$5,386,000	2	2	3	1	8	$125,000	0
St. Elizabeth's Medical Center of Boston	$4,500,000	6	5	1	0	3	$0	0
Cleveland Clinic Foundation	NA	111	29	20	29	3	$1,995,522	0
TOTALS:	**$2,110,957,455**	**1,106**	**801**	**398**	**957**	**355**	**$150,148,745**	**17**

OVERVIEW OF RESEARCH, DEVELOPMENT, AND TECHNOLOGY TRANSFER ACTIVITIES OF AMICUS CURIAE

Wisconsin Alumni Research Foundation ("WARF") was established as a non-profit entity to promote, encourage, and aid scientific investigation and research at the University of Wisconsin-Madison. To achieve this goal, its primary activities include promoting innovation, managing patents, and funding research. Founded in 1925, among its first actions was to patent Professor Harry Steenback's breakthrough discoveries in vitamin D. In 1927, WARF granted its first license for vitamin D supplements, which ultimately led to the worldwide elimination of rickets by the 1940's. Today, among WARF's most important patents are: the blood anticoagulant Warfarin; a coding process making pills easier to swallow; treatments for osteoporosis and cancer; magnetic resonance techniques; and a discovery known as the "Wisconsin Solution" that prolongs the use of transplant organs. All of WARF's 3,000 discoveries are administered with a commitment to continuing research, public education, and vigilance in protecting the public interest by enforcing quality control and preventing the unscrupulous exploitation of technologies.

The Regents Of The University Of California provides for technology transfer from ten campuses and five medical schools in the State, and three national laboratories operated by the University system on behalf of the U.S. Department of Energy. Currently, there are more than 3,000 ongoing research projects supervised by 13,000 principal investigators. These efforts in the last ten years have led to three Nobel laureates in a long list of pioneering research discoveries in biochemistry, bioengineering, cell biology, disease procedures, developmental biology, endocrinology, genetics, immunology, neurobiology, oral biology, pharmacy, and pharmacology. Examples of specific discoveries

include: the Cohen Boyer process for gene splicing (a co-invention of Stanford University and the University of California San Francisco ("UCSF")); the Hepatitis B vaccine (UCSF); a human growth hormone; and a method to treat aneurysms by use of a catheter instead of opening the skull (UCLA). UCSF also has contributed to cochlear implants to help the hearing impaired. UC Davis has contributed to a method detecting feline immune deficiency virus. Lawrence Livermore National Laboratory has contributed to a method for detecting chromosome abnormalities, now successfully commercialized through FDA approvals to a company dedicated to the technology. UC Irvine has contributed to a laser system to enhance treatment of skin conditions. UC Riverside has contributed to a new phosphorus fertilizer. UC Berkeley and UC San Diego have contributed to fluorescence detection systems used in manipulation of cells. UC Santa Barbara has contributed to a new atomic force microscope.

Massachusetts Institute Of Technology ("MIT") is a private, non-profit university, that includes Lincoln Laboratory, which has pioneered advanced electronics since its origin in 1951. MIT-Lincoln Laboratory has a long history of technology transfer application in the defense and civilian sectors, MIT-Lincoln Laboratory has produced nearly 500 patents and given birth to over 800 high-technology companies, which today are at the forefront of such diverse industries as multi-media software services, advance semi-conductor lithography, and medical services. For example, neurotechnology, based on a military target recognition techniques, is now used to detect abnormal pre-cancerous cells in Pap smears. Another neural network application uses image classification techniques to conduct risk assessment for bypass surgery in cardiovascular disease patients. In the area of binary optics, MIT Lincoln Laboratory has licensed the design and manufacture molds for implantable binary lenses and adaptive nulling for processing radar systems used in the support of hypothermic

treatment of tumors. Other radar technologies soon will be applied in FDA-approved Phase II clinical trials for the treatment of breast cancer. One of the newest research and industry partnerships initiated at MIT, includes the Center for Biomedical Engineering ("CBE"). The mission of CBE is to combine engineering with molecular and cellular biology to develop new approaches to biotechnology and foster research in this rapidly growing discipline. CBE has 45 faculty members from the Departments at MIT's Schools of Engineering and Science, the Whitehead Institute, Harvard and Boston University Medical Schools, and the Harvard-MIT Division of Health Sciences and Technology. Among the research accomplishments this past year include new developments in neural tissue engineering used to encapsulate cells such as neurons and chondrocytes.

Washington Research Foundation ("WRF") assists Washington State University research institutions with emerging technologies, through intellectual property management and start-up investment activities, primarily with local private technology companies. The University of Washington has over 90 specialized research centers and institutes, which focus on such areas as marina resources, transportation, women's health, and managing pain, which are supported by WRF. WRF also has been a leading institution in technology transfer partnering with local business, several of which are described below. Amnis Corporation, a Seattle-based start-up founded in 1998, is developing high throughput laboratory automation tools that use a novel molecule detection technology. Theorus Corporation, based in Seattle, is commercializing therapeutic ultrasound products that provide effective, non-invasive surgical management of benign and malignant lesions, trauma conditions and selected functional disorders. The first application of its TheraSeal™ System is arterial puncture sealing. EKOS Corporation, a Bothell, Washington medical device company, is developing technologies that use

localized ultrasound to facilitate, enhance, or control the delivery or activation of drugs at a targeted tissue site. Micronics, Inc., based in Redmond, develops and commercializes innovative healthcare products using the unique capabilities of Micro Electro Mechanical Systems (MEMS) technology. Corus Pharma, Inc., based in Seattle, develops pharmaceutical products that address unmet needs in infectious disease and respiratory disorders. Point of CareWare, a Bellevue, Washington start-up, develops, markets, and supports products designed to improve the operations and quality of care provided by Post Acute Care facilities. Confirma, Inc., based in Kirkland, Washington, is a medical device company focused on developing and marketing magnetic resonance data analysis software and database products, which help physicians make more informed decisions. The company's lead product enables radiologists to interpret MRI images with greater precision and confidence for staging, therapeutic monitoring, and detection of recurrent solid tumor cancers. Koronis Pharmaceutical, Inc. was founded in 1998 to discover and develop antiviral small molecule drugs, with a particular focus on therapies for chronic viral diseases including those caused by the human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). Lumera Corp. develops electro-photonic components based on proprietary polymer materials licensed from the University of Washington. nLight Photonics Corp., based in Seattle, is developing subsystems that will expand the capabilities and performance of optical networks. nLight's proprietary technology and manufacturing expertise will enable high-performance, cost effective networks. Intelligent Ion, based in Seattle, is developing a miniature mass spectrometer based on proprietary technologies developed at the University of Washington and California Institute of Technology/Jet Propulsion Laboratory. Intelligent Ion is focusing its products for applications in the chemical industry and environmental market. Ostex International, Inc., is

engaged in the discovery, development, and commercialization of diagnostics and therapeutics for diseases of the skeleton and connective tissues.

University Of Pennsylvania and its affiliate Center for Technology Transfer ("CTT") is at the forefront of efforts to move discoveries from the laboratory to the marketplace. CTT is involved in Internet and global telecommunication structures, new medical technologies, and pharmaceutical products and is currently working on discoveries that will shape the future in such exiting areas as: cognitive neuroscience; fuel cells; artificial vision; bioinformatics; nanotechnology; functional genomics; proteomics; medical imaging; MEMS; wireless technology; conductive polymers; genetic medicine; and natural language processing. Examples of technologies discovered at the University's laboratories that have been licensed for commercialization, either by a start-up venture or an established company include: neuronal cell transplants that treat stroke damage; plant cells engineered to be more efficient chemical factories; techniques that teach psychological resilience; micro-fluidics technology that move samples through multiple test sites for rapid analysis; synthesis technology using enzymes to produce a range of useful carbohydrates that have thousands of uses ranging from food additives to vaccines; computer-simulated human modeling providing manufacturers with a powerful new tool to optimize productivity; a technology to develop pharmaceutical approaches to managing disorders associated with myopia or nearsightedness; a technology that uses a combination of an adhesive with a patented fabric cuffs systems in horseshoes that distributes the weight of the horse over a broad area, reducing stress points; drugs that pre-condition heart cells for lower risk during cardiovascular procedures; non-invasive techniques that help heal fractures and bond fusions; a technology used to develop a vaccine to treat and prevent herpes simplex infections; and gene therapy that may hold the key to underlying diseases.

University Of Minnesota has been consistently recognized as a world-class institution of higher education and leader in the research community with pioneering faculty, research staff, and students who have made new discoveries and innovations in a wide array of disciplines including: agriculture; engineering; environmental and life sciences; and medicine. The University of Minnesota is also actively engaged in technology transfer affiliations. Net Perceptions™, a leading supplier of computer technology, received the first MIT Sloan E-Commerce Technology Innovator Award for innovations. Other significant efforts include a new aids drug based on anti-HIV components called carbovirs, discovered by Dr. Robert Vince at the University of Minnesota's College of Pharmacy. The University of Minnesota and the Mayo Foundation for Medical Education and Research also recently have licensed a technology for the diagnostic detection of tumors, particularly bre... cancer tumors utilizing the unique qualities of Vitamin B-12. In February 2000, the University of Minnesota-Duluth's Natural Research Institute helped form a partnership called NaturTek to glean valuable natural compounds from birch bark to be used in agrochemical, wood protection, coding materials, anti-corrosive and cleaning materials, lubricants and cutting materials, polymers, skin care products, nutraceuticals and pharmaceuticals.

The Board Of Trustees Of The Leland Stanford Junior University ("Stanford University"). The synthesis of teaching and research activities is fundamental to Stanford University. All faculty engage in scholarly research, most often in association with graduate students or advanced undergraduates. Stanford University is noted for its openness to interdisciplinary research, not only within the schools and departments, but also in its nine independent laboratories, centers and institutes. Stanford University is also known for

its pioneering efforts in structuring industry-university collaborations, and was recently awarded the Licensing Executive Society's inaugural Lifetime Achievement Award for those efforts. Several national research centers are located on the university's campus, including the Center for Advanced Study in the Behavioral Sciences, the National Bureau of Economic Research, and the Stanford Linear Accelerator Center (SLAC). There are more than 2,400 externally sponsored research projects throughout the university. Stanford University researchers have made many critical discoveries over the years, including: the synthesis of biologically active DNA in a test tube; the construction of a recombinant DNA molecule containing DNA from two different species; discoveries that led to magnetic resonance imaging; the invention of the klystron tube, a high frequency amplifier for generating microwaves; the construction of the first 6-million-volt accelerator for cancer treatment, making Hodgkin's disease and forms of cancer treatable; the invention of the laser; the first human heart transplant in the United States, followed by the first heart/lung transplant; the musical synthesizer widely used in electronic instruments; and the invention of the IQ test.

SUNY Research Foundation is a private, non-profit educational corporation responsible for the administration of externally-funded contracts and grants for and on behalf of the State University of New York. In 1999-2000, SUNY Research Foundation sponsored more than 7,500 programs to facilitate research, education, and public service at 30 state-operated locations. The State University of New York's research contributions are helping to solve some of today's most urgent problems. At the same time, contracts and grants received by university faculty directly benefit the economic development of the regions in which they are located. The State University of New York researchers pioneered nuclear magnetic resonance imaging and the supermarket bar code scanner, introduced time-lapse photography of forestry

subjects, isolated the bacteria that causes Lyme disease, and developed the first implantable heart pacemaker. Other researchers continue important studies in such wide-ranging areas as breast cancer, immunology, marine biology, sickle-cell anemia, robotics, and make hundreds of other contributions, inventions and innovations for the benefit of society.

Cornell Research Foundation, Inc. ("CFR") is a non-profit subsidiary of Cornell University responsible for the evaluation, protection, and commercialization of innovations resulting from its research programs. CRF has issued over 800 active licenses to more than 250 companies and has helped create a number of start-up companies. The products of these enterprises include: flat-screen TV's; Web-based video editing techniques; methods for improving agricultural crops; novel ways of producing Internet switching devices; a fortified powdered orange drink to improve children's growth and mental development; biodegradable hydro-gels that deliver medications inside the body; and anchor skin and vascular grafts; a new light weight polymer material reinforced with glass or carbon fibers stronger than steel; self-guided robots that can "think" -- and play championship soccer; behavioral economics techniques that analyze how and why people mismanage money; a method of eliminating deadly E-coli 0157:H7 bacteria from meat; and ways by which on-shore pollution causes disease in the ocean.

University Of Florida established the non-profit University of Florida Research Foundation, Inc. in 1986 to promote, encourage, and provide assistance to the research activities of university faculty, staff, and students. Its mission is to provide the means by which research can be conducted flexibly and efficiently and discoveries, inventions, processes, and work products can be transferred from laboratory to the public. The funds generated by licensing such technologies are used to enhance research at the

University of Florida, which has more than 100 service and education centers, bureaus, and institutes. More than two dozen faculty are members of the National Academies of Science and/or Engineering, the Institute of Medicine, or a counterpart in another nation. Among its most prominent research affiliates are the University of Florida's Brain Institute, Health Science Center, National High Magnetic Field Laboratory, and Whitney Marine Laboratory.

University of Utah ranks among the top 25 public research universities in the United States. In addition to internally supported research, the University receives more than $242 million dollars from federal, state, and private sources in direct support of specific research projects. The University conducts and supports research at over 40 internal centers and institutes, such as the Huntsman Cancer Institute, the Center for Human Genome Research, the Institute for High Energy Astrophysics and the Tanner Center for Humanities. In 1967 the University of Utah Technology Transfer Office ("TTO") was established under the Vice President for Research to manage the University's intellectual property and to help faculty and staff realize the economic value of their inventions. The TTO patents inventions developed at the University and seeks appropriate licensees in order that the benefit of these technologies be made available to the general public. The University of Utah owns approximately 291 active patents, and has approximately 146 active licenses. More than 60 companies have been established based on University of Utah technologies licensed by the Technology Transfer Office which has led to local and national economic benefits by creating over 3,600 jobs and generated more than $176 million in investment.

Oregon Health & Science University ("OSHU"). OHSU's fundamental purpose is to improve human health. It accomplishes this mission by: educating physicians, dentists, nurses, biomedical scientists and allied health professionals;

conducting basic and applied research on the prevention, treatment and cure of diseases and injuries; providing comprehensive, innovative and cutting-edge patient care; and improving access to care and education through its public service and outreach activities. In the past decade, some of the nation's most accomplished scientists have flocked to OHSU. Accordingly, OHSU has a well-earned reputation as a premier biomedical research institution and now maintains multimillion dollar, multiyear training and research grants in such areas as neurodegenerative disease (*e.g.*, Alzheimer's and Parkinson's), addictive disorders, stress, cancer, heart disease, genetic disorders, stroke, sleep disorders, neurosciences, toxicology, physiology and pharmacology, eye disorders, hearing loss, hypertension and clinical nutrition. OHSU scientists announce breakthroughs and innovations about every seven days. Approximately 1,500 scientists are working on basic and applied research projects at present.

University Of Texas-Medical Branch ("UTMB") was established in 1891 and today is an international leader in bio-medical research with a broad range of promising applications for patient care. Research at UTMB is multi-disciplinary, including basic scientists, clinicians, faculty, and students from all areas of medicine working together to share information, facilities, and other resources that focus on research, which addresses cancer, environmental toxicology, structural biology, molecular sciences, aging, and molecular cardiology. Current research activities include investigation of new and resurgent infections, tropical diseases, neuroscience, burns and wound healing. UTMB is also home to the National Student Research Forum, which plays a pivotal role in support and education of the nati 's scientific leaders.

University Of Vermont ("UVM") is the state's only comprehensive research university. It is a national leader in

identifying effective practices for educating children with disabilities and the university's research has helped stop smoking, promote effective breast cancer screening, and prevent of aids and diabetes. Environmental research has been critical in lake and river quality, tracking fish senses, and fish breeding habits and health. UVM has been active in the transfer of technologies to Vermont business, which has created jobs and support innovation. For example, it has provided technical support to a Vermont company in x-ray lithography and the university is linked with a business that is experimenting in polymer to address a semiconductor adhesion problem. UVM research also has developed optical switches for communication systems. UVM plays a central role in the Vermont Technology Council, which has helped create links with business, academia, and state government to benefit Vermont's economy.

University Of Texas M.D.-Anderson Cancer Center-Houston is one of the leading cancer treatment and research facilities in the world and one of the three comprehensive cancer centers designated by the National Cancer Act of 1971. Research has been the driving force that has propelled the University of Texas M.D. Anderson Cancer Center's international reputation for scientific excellence. M.D. Anderson's scientists are in the vanguard of understanding the meaning of the inherited flaws in various genes responsible for cancer. The most recent findings for clinical interventions focus on genes involved in cancer initiation and proliferation. Of the estimated 100,000 genes within every person, only 400 appear to be critical for cell division and growth. Identifying the molecular mutations or malfunctions in those key genes is now possible. A cancer genomics laboratory at M.D. Anderson supports research to expand molecular therapies. One fruitful area of gene-based translational research concerns the p53 tumor suppressor gene, which is either missing or mutated in a majority of human cancers. Landmark research reported from M. D.

Anderson during the 1990s included the first successful correction of a defective p53 gene in lung cancer patients and extension of that gene therapy method to treat head and neck, prostate, bladder and other cancers. Progressively positive results have been observed in expanding clinical trials that combine p53 gene therapy with chemotherapy and radiation. Other techniques to replace or repair abnormal genes also have been developed at M. D. Anderson for brain tumors as well as breast and ovarian cancers. Several types of gene therapies have progressed from laboratory studies in experimental animals to clinical trials in only a few years because of the collaboration among research and clinical faculty and the institution's capacity to care for a large number of patients, including those with uncommon cancers.

Cold Spring Harbor (Woods Hole Oceanographic Center). Cold Spring Harbor Laboratory scientists also work with researchers at other laboratories and universities, and collaborate with their counterparts in the biotech and pharmeceutical industries in a quest to translate advances in basic research into applications that are life-saving and life-enriching. Current areas of research are: cancer research; neurobiology; genetics & bioinformatics; and plant genetics. Another major effort is to understand molecular aspects of plant developmental genetics and genomics. The plant group at CSH is expanding upon the Nobel prize-winning work done by Barbara McClintock in the 1940s, 50s and 60s; the transposable genetic elements, or "jumping genes," that she discovered are the basis for much of plant genetics research today. One of the most exciting and complex projects in this area is the study of the molecular biology of learning and memory. Cold Spring Harbor scientists are making strides in understanding the physiological basis of learning and the formation of long term memories. Cold Spring Harbor Laboratory is also involved in genome research and recently entered into a global collaboration to map and sequence the entire genome of a flowering plant for the first time ever.

The American Council On Education ("ACE"), founded in 1918, is the nation's coordinating higher education association. ACE is dedicated to the belief that equal educational opportunity and a strong higher education system are essential cornerstones of a democratic society. ACE's 1,800 members include accredited, degree-granting colleges and universities from all sectors of higher education and other education and education-related organizations. ACE is a forum for the discussion of major issues related to higher education and its potential to contribute to the quality of American life. The American Council on Education represents regularly before the United States Supreme Court, other federal courts, Congress, and federal agencies.

The Association Of American Universities was founded in 1990 by a group of 14 universities offering the Ph.D. degree. Today, the Association has 61 American universities as members, approximately half of which are public institutions and half are private. The Association assists members in developing national policy positions on issues that relate to academic research and graduate and professional education. In matters of national science and research policy, the Association is actively involved with a broad cross-section of organizations, including the National Academies of Science and Engineering and the Institute of Medicine.

The National Association Of State Universities And Land-Grant Colleges was founded in 1887 and is the nation's oldest higher education institution, including public universities, land-grant institutions, and many of the nation's public university systems. As of October 2000, Association membership included 212 institutions, including 75 land-grant universities (of which 17 historically were designated as black public institutions under Second Morrill Act of 1890) and 28 public higher education systems. Tribal colleges became land-grant institutions in 1994 and 30 are

represented by the Association through the membership of the American Indian Higher Education Consortium.

Council On Governmental Relations ("COGR") is an association of 144 research-intensive universities in the United States. It is a source of critical information on current and emerging issues for its members and agencies sponsoring their research activities. COGR is a leading advocate for policies that support the conduct of research at the highest standards and sound and informed decision-making on issues affecting the research and education community. COGR works with federal agencies and research sponsors to develop a common understanding of the impact that policies, regulations and practices may have on the research and training programs conducted by the membership.

Research Corporation Technologies is an independent technology management company that provides commercialization services to academia and industry and has been pivotal in the success of many important pharmaceuticals, diagnostics, biotechnology products, new materials and processes.